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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/602,812	06/23/00	ADAMS C	P1467R2

HM22/1002

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EXAMINER	
HUNT, J	
ART UNIT	PAPER NUMBER
1642	7

DATE MAILED: 10/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/602,812	Applicant(s) ADAMS ET AL.	
	Examiner Jennifer E Hunt	Art Unit 1642	

-- The MAILING DATE of this c mmunication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-59 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-59 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, 12, 13, 16-22, 24-29, and 34, drawn to a method of treating cancer using an antibody which binds ErbB2, classified in class 424, subclasses 130.1 and 178.1.

II. Claims 10-11, 14-15, and 30-31, drawn to a method of treating cancer using an antibody which binds ErbB2, and a chemotherapeutic agent, classified in class 424, subclass 130.1 and class 514, subclass 1.

III. Claim 23, drawn to a method of treating cancer using an antibody which binds ErbB2 and an "agent", classified in class 424, subclasses 130.1 and 178.1, and class 514, subclasses 1 and 2.

IV. Claims 32-33, drawn to a method of treating cancer using an antibody which binds ErbB2 and a second antibody, classified in class 424, subclasses 130.1 and 155.1.

V. Claims 35-36, and 39-53, drawn to an antibody which binds ErbB2 and corresponding article of manufacture, classified in class 424, subclass 155.1.

VI. Claims 37-38, drawn to an article of manufacture comprising a first antibody which binds ErbB2 and a second antibody which binds ErbB2, classified in class 424, subclass 155.1.

VII. Claims 54-59, drawn to a polynucleotide encoding an antibody which binds ErbB2 and corresponding vector, host cell, and method of making the antibody, classified in class 536, subclass 23.53, and class 435, subclass 320.1 and 325.

The inventions are distinct, each from the other because of the following reasons:

The methods of Groups I-IV are distinct. The methods all require unique materials, and will effect a distinct therapeutic response. Group I treats cancer using an antibody alone. Group II treats cancer using an antibody and a chemotherapeutic agent. Group III treats cancer using an antibody and an "agent". Group IV treats cancer using an antibody and a second antibody. The art teaches that different combination therapies have variant results, with many combinations of drugs counteracting each other, while others produce a synergistic therapeutic result. Thus the variant combinations require distinct searches and grounds of consideration.

The products of Groups V-VI are distinct. Group IV comprises a single antibody. Group V comprises two specific antibodies. Group VII comprises a nucleic acid molecule, and corresponding vector, host cell, and method of making an antibody. The physical structures of these products are distinct and the products themselves exhibit distinct physiological effects. Further, the combination of two antibodies is distinct from a single antibody alone for the reasons set forth above.

Inventions of Groups V and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another

materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group V can be used for a materially different process, such as a diagnostic test, or isolation of polypeptide.

Inventions VI and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies of Group IV can be used for a materially different process, such as a diagnostic test, or isolation of polypeptide.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for any other Group, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

If any of Groups I-VII are elected, applicant must further elect a species of antibody:

A) Where the antibody is conjugated with a cytotoxic agent.

B) Where the antibody is not conjugated with a cytotoxic agent.

Conjugated vs. non-conjugated antibodies have different physical structures, chemical properties, and physiological activities.

If any of Groups I-IV are elected, applicant must further elect a cancer which is being treated:

C) Colorectal, rectal or colon.

D) Lung

E) Breast

Different types of cancers have different mechanisms of action, and require distinct treatment protocols.

If Group II is elected, applicant must further elect a single specific chemotherapeutic drug, for example, any of the individual drugs listed in claims 11, 15, and 31, or listed on page 18 of the specification.

All of the chemotherapeutic agents recited in the claims and specification have vastly different structures and mechanisms of action.

If Group IV is elected, applicant must further elect a specific agent. For example, a *specific* antibody, or *specific* chemotherapeutic drug, or one of the numerous agents listed at pages 18-20 of the specification. For example, docetaxel, IL-2, or digoxin would each be considered a species. A general category such as "chemotherapeutic agent", "cytokine", or "cardioprotectant" would not be

considered a species. *Note that a selection of a general category will be considered non-responsive.

All of the agents recited in the claims and specification have vastly different structures and mechanisms of action.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable

over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E Hunt whose telephone number is (703) 308-7548. The examiner can normally be reached on Monday-Friday, 6-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

Jennifer E Hunt
Examiner
Art Unit 1642

jeh
September 27, 2001

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600